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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,703	07/09/2003	Stephen J. Benkovic	00-387-P	5892

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MCDONNELL BOEHNNEN HULBERT & BERGHOFF LLP  
300 S. WACKER DRIVE  
32ND FLOOR  
CHICAGO, IL 60606

EXAMINER

TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/615,703

Applicant(s)

BENKOVIC ET AL.

Examiner

MY-CHAU T. TRAN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-11, drawn to a method for protecting an animal against a microbe-induced disease, classified in class 514, subclass 64.
  - II. Claims 12-22 and 41-44, drawn to a method of treating a microbe-induced condition, classified in class 424, subclass 278.1.
  - III. Claims 23-40, drawn to a method of reducing bacterial virulence, classified in class 435, subclass 15.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Group I, Group II, and Group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions, i.e. methods, as claimed have method steps that are not capable of use together and have different designs and effects. For example, Group I employ the method step of inhibiting DNA methyltransferase activity in the microbe. Group II employ the method step of administering to the mammal a therapeutically effective dose of a methyltransferase inhibitor with a pharmacological excipient. Group III employ the method step of contacting bacteria with an agent that alters the bacteria's native level of DNA methyltransferase activity thereby inhibiting virulence of the bacteria. That is Group II requires the composition (i.e. a reagent) of a methyltransferase inhibitor with a pharmacological excipient whereas neither Group I nor Group III required a reagent with a pharmacological excipient, and as a result the Groups have different

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designs. Group III requires that the reagent alter the bacteria's native level of DNA methyltransferase activity whereas neither Group I (i.e. protecting the mammal) nor Group II (i.e. treating the mammal) required this effect, and as a result the Groups have different effects. Therefore, the methods as claimed are not capable of use together and they have different designs and effects, and the restriction among these methods is proper.

3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

4. This application contains claims directed to patentably distinct species of the claimed invention for Groups I-III. Election of species is required as follows.

5. *If applicant elected the invention of Group I*, applicant is required to elect from the following patentably distinct species:

- a. A *single specific species* of 'type' of DNA methyltransferase activity, e.g. expression of DNA methyltransferase (i.e. see claims 2 and 3).
- b. A *single specific species* of microbe, e.g. *Bacillus* species (i.e. see claims 7-11).

The species are independent or distinct, each from the other, because they have different chemical structure and/or physiochemical properties and would be capable of separate manufacture and/or use. Moreover, the above species can be separately classified, and would necessitate different and separately burdensome manual and computer bibliographic and structure searches in both patent and non-patent areas.

Applicant is required under 35 U.S.C. 121 to elect *a single disclosed species* of the above species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 1 is generic.

6. *If applicant elected the invention of Group II*, applicant is required to elect from the following patentably distinct species:

- c. *A single specific species* of 'type' of DNA methyltransferase activity, e.g. expression of DNA methyltransferase (i.e. see claims 13 and 14).
- d. *A single specific species* of microbe/condition, e.g. *Agrobacterium* species (i.e. see claims 18-22, 42, and 43).

The species are independent or distinct, each from the other, because they have different chemical structure and/or physiochemical properties and would be capable of separate manufacture and/or use. Moreover, the above species can be separately classified, and would necessitate different and separately burdensome manual and computer bibliographic and structure searches in both patent and non-patent areas.

Applicant is required under 35 U.S.C. 121 to elect *a single disclosed species* of the above species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 12 and 41 are generic.

7. *If applicant elected the invention of Group III*, applicant is required to elect from the following patentably distinct species:

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- e. A *single specific species* of 'type' of bacteria's native level of DNA methyltransferase activity e.g. methylation of adenine (i.e. see claims 24-26).
- f. A *single specific species* of bacterium (e.g. see claims 35-39).

The species are independent or distinct, each from the other, because they have different chemical structure and/or physiochemical properties and would be capable of separate manufacture and/or use. Moreover, the above species can be separately classified, and would necessitate different and separately burdensome manual and computer bibliographic and structure searches in both patent and non-patent areas.

Applicant is required under 35 U.S.C. 121 to elect *a single disclosed species* of the above species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 23 is generic.

8. Applicant is advised that a reply to this requirement *must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added*. An argument that a claim is allowable or that all claims are generic is considered *nonresponsive* unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. *If claims are added after the election, applicant must indicate which are readable upon the elected species*. MPEP § 809.02(a).

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10. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention. Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

My-Chau T. Tran  
February 19, 2006

